Section 5 - 510(k) Summary

APPLICANT:	JG Spine, LLC
Contact Person:	Greg Smith, Manager 309 N Sea Lake Lane Ponte Vedra Beach, FL 32082 Tel: (904) 509-6030
Application Correspondent:	Kapstone Medical, LLC 100 E. South Main St. P.O. Box 1458 Waxhaw, NC 28173
Contact Person:	John Kapitan, President, Kapstone Medical LLC Tel: (704) 843-7852 Fax: (704) 831-5316 Email: jkapitan@kapstonemedical.com
PROPOSED TRADE NAME:	SureFix Interspinous Fusion System
PREPARATION DATE:	08/08/13
DEVICE CLASSIFICATION:	Class II
CLASSIFICATION NAME:	Spinal Interlaminal Fixation Orthosis
REGULATION NUMBER:	888.3050
PRODUCT CODE:	PEK
DEVICE DESCRIPTION:	The JG Spine SureFix Interspinous Fusion System device is a family of posterior, non-pedicle, supplemental fixation devices that are manufactured from Titanium alloy (per ASTM F136). More specifically, these devices are interspinous process implants that are offered in a variety of diameters and lengths and are clamped to two consecutive non-cervical spinous processes. The system is to be implanted from the posterior approach.
INDICATIONS FOR USE:	The SureFix Interspinous Fusion System is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1 inclusive). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. The SureFix Interspinous Fusion System is intended for use with bone graft material, and not for stand-alone use.
MATERIALS:	Medical grade Titanium alloy.
PREDICATE DEVICES:	Lanx Spinal System (K100935) Axle Interspinous Fusion System (K101471)
TECHNOLOGIC CHARACTERISTICS:	The fundamental scientific principles and technological characteristics of the SureFix Interspinous Fusion System, including the intended use, general design, and sizes of the devices are the same as, or similar to, the predicate devices listed

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above.

PERFORMANCE DATA: Testing of the SureFix Interspinous Fusion System to demonstrate substantial equivalence included construct static compression bending, static torsion and dynamic compression bending according to ASTM F1717-11, and component level testing according to ASTM F543-07.

SAFETY & EFFECTIVENESS: The JG Spine SureFix Interspinous Fusion System is substantially equivalent to the predicate Lanx device (K100935) and X-Spine device (K101471). The devices have the same "Indications for Use", share similar technological characteristics, are available by prescription only, and are provided non-sterile for single-use only. Materials of manufacture are also similar. Performance testing has shown that the SureFix Interspinous Fusion System is substantially equivalent to the predicate devices.

CONCLUSION: The SureFix Interspinous Fusion System is both a safe and effective device and is substantially equivalent to the predicate devices based on testing and comparison.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

August 9, 2013

JG Spine, LLC
John Kapitan
100 E. South Main St.
Waxhaw, NC 28173 US

Re: K124014
Trade/Device Name: SureFix Interspinous Fusion System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: July 8, 2013
Received: July 12, 2013

Dear Mr. Kapitan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Division Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 - Indications for Use Statement

Device Name: SureFix Interspinous Fusion System

The SureFix Interspinous Fusion System is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1 inclusive). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. The SureFix Interspinous Fusion System is intended for use with bone graft material, and not for stand-alone use.

Prescription Use ____X____ or Over-The-Counter Use _____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colin O'Neill for RPJ

(Division Sign-Off)
Division or Orthopedic Devices
510(k) Number: K124014